

### **Remarks/Arguments**

1. Claims 1-3, 5-8, 10-11, 13-16, 18-21, 23-24 and 26-31 remain in the application.

2. Claims 4, 9, 12, 17, 22, 25 and 32 have been canceled.

3. The Examiner has objected to Claims 13 and 26 as being dependent upon a rejected base claim. However, the Examiner has acknowledged that Claims 13 and 26 would be allowable if they were to be rewritten in independent form including all of the limitations of the base claim and any intervening claims. With respect to this objection, it is submitted that Claims 13 and 26 have been amended to include all of the substantive limitations that the Examiner deemed to be allowable, including the limitation that the substrate being coated is an edible substrate in the form of a tablet. Accordingly, in view of the amendments to Claims 13 and 26, this objection is traversed and allowance of Claims 13 and 26 is requested.

4. The Examiner has rejected Claims 31 and 32 under 35 U.S. C. 102(e) as anticipated by, or in the alternative, under 35 U.S.C. 103(a) as obvious over Benoit (6,183,783). Claim 32 has been canceled. However, Claim 31 has been amended and remains in the application, and with respect to Claim 31, this rejection is traversed and reconsideration thereof is requested.

In making the above rejection, the Examiner has indicated that Benoit relates to a method of preparing microcapsules of active material coated with a polymer, wherein the microcapsules are formed by using CO<sub>2</sub> to extract the solvent from a polymer solution and to bring about a gradual precipitation of the polymer to thereby form recoverable microcapsules.

While the Applicants do not take serious exception to the Examiner's characterization of Benoit, the Applicants submit that Benoit in no way discloses nor renders obvious the subject matter that is set forth in Claims 31. For example, while Benoit is concerned with preparing microcapsules comprising a small particle size active substance coated with a layer of polar polymer, the Applicants are concerned with applying an edible coating on a larger size edible preformed solid substrate, such as a piece of candy, a vitamin tablet, a pharmaceutical tablet or the like. In this regard, it will be noted that the active substance that Benoit intends to microencapsulate is provided in the form of a powder of small particle size, "typically on the order of a few microns, and more generally from approximately 0.1  $\mu$ m to approximately 800 $\mu$ m." (See, Col. 6, lines 10-13 of Benoit).

Another substantive difference between Benoit and the presently claimed method is that Benoit brings into contact with a suspension comprised of (a) of micron sized powder active material and (b) a solution of (i) substantially polar polymer and (ii) organic solvent, whereas the claimed method sprays a coating composition comprised of a concentrated solution comprising (i) solvent, (ii) edible polymer and (iii) onto an edible substrate. At no time during the formation of the sprayable coating composition of the present invention is the edible substrate mixed with the edible polymer, solvent or liquid CO<sub>2</sub>. This important distinction is readily discerned when one considers the vastly different function of the liquid CO<sub>2</sub> in Benoit and in the present method. In Benoit, the liquid CO<sub>2</sub> functions to extract the solvent from the polymer solution in a controlled way and to provide for the polymer's coacervation and precipitation onto the micron sized active material, whereupon the resulting CO<sub>2</sub>/solvent mixture may be discharged and the microencapsulated active material may be recovered; whereas in Claims 31, the liquid CO<sub>2</sub> functions to reduce the viscosity of the concentrated polymer solution so as to form a coating composition (comprised of the concentrated polymer solution and the liquid CO<sub>2</sub>) that can be atomized and sprayed onto a edible substrate which is physically distinct, i.e., not pre-mixed, with the coating composition.

In view of the foregoing and other substantive differences, it should be readily apparent that Benoit does not, and can not, anticipate the method of spray coating an edible preformed substrate that is set forth in Claim 31. It also should be apparent that nothing in Benoit could possibly suggest the subject method of spray coating an edible preformed substrate as being obvious to one of ordinary skill in the art. Accordingly, it is submitted that the rejection of Claim 31, as amended, is not sustainable and that it should be withdrawn, and such action is requested.

5. The Examiner has rejected Claims 31 and 32 under 35 U.S. C. 102(b) as anticipated by, or in the alternative, under 35 U.S.C. 103(a) as obvious Thies et al. (5,512,231). Claim 32 has been canceled. However, Claim 31 has been amended and remains in the application, and with respect to Claim 31, this rejection is traversed and reconsideration thereof is requested.

In making the above rejection, the Examiner has indicated that Thies et al. discloses forming cellulose acetate articles using a supercritical fluid, The Examiner has also pointed out that in Example 1, Thies et al. disclose cellulose acetate mixed in a solvent system containing supercritical carbon dioxide and ethanol, and that the Applicants' claims appear to differ from the reference by reciting process limitations which do not carry weight in product claims.

In this regard, it will be noted that Claim 31, as originally filed, purported to claim a liquid sprayable coating composition. However, all of the elements of the original Claim 31 were set forth as method steps beginning with a gerund. Original

Claim 31, in substance, was a product by process claim. In order to avoid confusion, the preamble of Claim 31 has been amended to clearly recite that Claim 31 relates to a sprayable coating composition which is prepared by specifically defined process steps. It is submitted process limitations may carry patentable weight in product by process claims.

Claim 31, as amended, relates to a sprayable liquid coating composition that is prepared by mixing (a) a concentrated solution of an edible polymer in a solvent, wherein the edible polymer comprises from about 45 to about 75 wt.% of the concentrated solution, together with (b) a sufficient amount of supercritical carbon dioxide to reduce the viscosity of the resulting mixture to less than 150 cps.

There is no such composition either disclosed or suggested in Thies et al. Rather, Thies et al. relates a method of preparing cellulose articles, such as filaments, tow or the like, by extruding through the orifices of a spinneret and into a precipitating bath or evaporative atmosphere a solution that is formed by dissolving cellulose acetate in a solvent made up of 5 to 50 wt.% carbon dioxide and from 50 to 95 wt.% of a compatible solvent, such as acetone, triacetin, ethanol or methanol. There is no generic statement in Thies et al. as to the concentration of the cellulose acetate solution. However, such solutions (which are referred to as a "dope" in the art), typically are quite dilute. This is consistent with the disclosure in Example 1 in Thies et al., wherein it is stated that: "The solids concentration [of the cellulose acetate solution] is in the [range of] 2-4% by weight of polymer to solvent." (See, Col. 3, lines 3-5 of Thies et al.). There also is no statement in Thies et al. as to the viscosity of the cellulose acetate solution that is to be extruded to form cellulose acetate articles. How then could Thies et al. suggest to one of ordinary skill in the art to form a sprayable liquid coating composition by first forming a concentrated solution of an edible polymer and a solvent, such as ethanol, and then adding an amount of supercritical carbon dioxide to the concentrated solution to reduce the viscosity of the resulting mixture to less than 150 cps? The answer should be clear. Thies et al. does not, and can not, make such a suggestion. Accordingly, it should be apparent that the rejection of Claim 31 in view of Thies et al. is unsound and that it should be withdrawn.

6. The Examiner has rejected Claims 1-12, 14-25 and 27-32 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an edible substrate, does not reasonably provide enablement for any and all substrates.

Of the rejected claims, only Claims 1, 14, 29, 30 and 31 are independent claims, and of these, only Claims 1, 14, 29 and 30 include the step of coating a substrate (Claim 31 relates to a sprayable liquid coating composition and does not recite a substrate on which the coating composition is to be applied; however, even that claim recites that the coating composition comprises an edible polymer). Each of the independent claims has been amended to set forth that the substrate being coated is

an edible preformed solid substrate, which is intended to include a wide variety of preformed substrates, such as confections, e.g., M&M™ candy pieces, Chicklets™ gum pieces, or the like, and tablets, e.g., vitamin tablets, pharmaceutical tablets, nutraceutical tablets, or the like. It is submitted that all of the claims remaining in the application now comply with the requirements of the first paragraph of 35 U.S.C. 112

The Examiner has requested clarification and correction of the declaration which claims priority on provisional application 60/228906, rather than on 60/228,966. The Examiner is correct. The claim to priority is based on provisional application 60/228966, and a new declaration needs to be filed to correct the error. A new declaration has been prepared for execution by the Applicants, and it shall be filed in due course.

In summary, and except for the new declaration, it is submitted that all of the pending claims are in condition for allowance, and Applicants request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read 'Anthony J. De Laurentis', is written over a horizontal line.

Anthony J. De Laurentis  
Attorney for Applicants  
Reg. No. 24,757

Anthony J. De Laurentis  
2001 Jefferson Davis Highway, Suite 311  
Arlington, VA 22202  
Tel.: (703) 415-1077